RECEIVED
CENTRAL FAX CENTER
AUG 2 3 2006

REMARKS

Claims 1-11 remain in the application. Claims 12-29 have been cancelled, without prejudice.

Claims 1 and 7 have been amended to more clearly emphasize that the claimed methods are limited to the administration of certain long-chain n-3 polyunsaturated fatty acids specifically to treat obesity and overweight in mammals that are obese or overweight. Support for this amendment can be found in Applicants' Specification at page 1, lines 3-6; and at page 2, lines 17-21.

Claims 4 and 9 have been amended to replace the term "during a growth phase" with the population to which such growth phases otherwise pertain: infants, children, and adolescents. Support for this amendment can be found in Applicants' Specification at page 19, lines 10 and 11.

Claim 7 has been amended to more clearly characterize the claimed embodiment as one directed to "decreasing" appetite rather than "modulating" it. Support for this amendment can be found in Applicants' Specification at page 15, lines 18-21.

Invention Synopsis

Claims 1-11 are directed to methods for decreasing the appetite of an overweight or obese mammal comprising enterally administering to said mammal an amount of long-chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal, wherein the polyunsaturated fatty acid is administered in the form of a triacylglycerol to treat obesity or overweight in mammals that are obese or overweight.

The above embodiment of the present invention is based upon the discovery that triacylglycerol esters of long chain n-3 polyunsaturated fatty acids reduce appetite in mammals, and can thus be used to treat obesity or overweight in individuals who are otherwise obese or overweight.

Examiner Interview

Applicants' undersigned attorney gratefully acknowledges the USPTO interview granted by Examiners Leslie A. Royds and Ardin Marschel on August 18, 2006, during which the pending prior art rejections and cited references were discussed. The interview summary, as drafted by the Examiner, accurately reflects the substance of the interview, the essence of which is also embodied in the following remarks.

Rejection under 35 USC 112

Claims 7-11 have been rejected under 35 USC 112, second paragraph, for reciting the term "modulating" as it appears in the phrase "for modulating the appetite of a mammal." The Examiner contends that "modulating" is indefinite since it could mean either an increase or decrease in appetite.

Responsive to this rejection, and upon entry of the amendments presented, the term "modulating" has been replaced with the term "decreasing." Applicants submit that claims 7-11, as amended, are in full compliance with the definiteness requirements of 35 USC 112. Applicants respectfully request withdrawal of this rejection.

Rejection under 35 USC 102

Claims 1-4, 12-15, 18-21, 24, 25, 27, and 28 have been rejected under 35 USC 102(b) as being anticipated by U.S. Patent 4,920,098 (Cotter et al.). Claims 7-9 have also been rejected under 35 USC 102(b) as being anticipated by U.S. Patent 6,200,624 (Mazer et al.)

The Examiner contends that the applied prior art references, each taken separately, teaches the identical steps of those presently claimed - the enteral administration of a composition comprising long-chain n-3 polyunsaturated fatty acids, as triacylglycerols. Applicants respectfully traverse these rejections as they would apply to the remaining amended claims.

Cotter et al. discloses nutritional compositions comprising at least one of gamma linolenic acid [n-6], eicosapentaenoic acid [n-3], docosahexaenoic acid [n-3], sterodonic acid, and linolenic acid [n-3 or n-6] (see Cotter et al., Abstract). Cotter et al. discloses the use of such compositions in individuals having or at risk of developing atherosclerotic, vascular, cardiovascular, or thrombotic diseases. (see Cotter et al., col. 1, lines 12-18).

Mazer et al. discloses nutritional compositions comprising triacylglycerol esters of arachidonic acid [n-6] and docosahexaenoic acid [n-3]. (see Mazer et al., Abstract). The formulas can be used as infant formulas or as adult nutritionals (see Mazer et al., col. 1, lines 9 and 10).

The Examiner contends that the claimed appetite reduction methods are really just an attempt to claim an inherent benefit from an otherwise known method - the enteral administration of long chain n-3 polyunsaturated fatty acids from triacylglycerol esters. To further emphasize the distinction of the present claims over the applied prior art, the claims have now been amended to recite that the appetite reduction is for the treatment of obesity or overweight in mammals that are obese or overweight. Such a use is neither disclosed nor suggested by either reference.

Although both references disclose compositions containing long chain n-3 polyunsaturated fatty acids, including triacylglycerol ester forms, neither discloses the use of such compositions to reduce appetite for treating obesity or overweight in obese or overweight individual, a key limitation to which all claims are limited.

Instead, Cotter et al. teaches the use of such compositions for treating or preventing atherosclerotic, vascular, cardiovascular, and thrombotic diseases (see Cotter et al., col. 1, lines 12-16), and Mazer et al. teaches the use of such compositions to provide nutrition to infants and adults (see Mazer et al., column 1, lines 7-13).

During the USPTO interview, the examiner expressed concern regarding the similarity between the Cotter et al method and the presently claimed method. Specifically, since the present claims are directed to treating obesity and overweight, the Examiner points out that such treatment should also have a positive impact on cardiovascular health, the very benefit to which the Cotter et al. teaches.

Applicants would like to emphasize that, although there is potential overlap between the ultimate health benefits of the two methods, there is no overlap between the specific diseases or conditions treated by each. Cotter et al. teaches a method to improve vascular health by affecting platelet function, vessel constriction, and serum cholesterol levels - not weight reduction (see Cotter et al., col. 2, lines 22-28). The present claims, by contrast, recite a method of treating obesity or overweight in individuals who are obese or overweight, by affecting appetite.

Moreover, not only does Cotter et al. fail to teach weight reduction, it actually teaches away from weight reduction by advocating increased energy consumption for individuals with various vascular diseases. To that point, Cotter et al. states:

> "Not only are patients with congestive heart failure and other vascular diseases **underweight** [emphasis added] with poor nutritional status, but their energy requirements are greatly in excess of a normal individual's energy requirements." (col. 1, lines 67 and 68; col. 2, lines 1-3). "

Cotter et al. goes on to provide examples of such individuals (Examples 1-4; cols. 8-10), all of whom were given high calorie formulations at 2.0 kcal/ml (see col. 7, Tables II and III).

In view of the Cotter et al. disclosure as noted above, the skilled artisan would not then select the n-3 long chain polyunsaturated component from the Cotter et al. compositions to reduce appetite and treat obesity and overweight in accordance with the present claims. This is especially the case for the many overweight individuals who are otherwise healthy and not suffering from any cardiovascular or other type of vascular disease.

The Examiner also contends that Cotter et al. inherently anticipates the present claims, because original claims 4, 9, 15, and 21 recited methods of using such compositions during the "growth phase" of an individual. The Examiner contends that such a "growth phase" would occur throughout an individual's life, so that the claimed method is essentially a method of administering the selected composition at anytime, which would then be anticipated by Cotter et al. (which discloses limited use for the treatment or prevention of certain diseases).

Applicants' submit that the term "growth phase" as originally recited in claims 4, 9, 15, and 21 does not apply at all times to all individuals. Instead, it refers to periods of rapid growth, such as during infancy, childhood and adolescence (see Applicants' Specification, page 19, lines 10 and 11). To further emphasize the above point, Applicants have amended claims 4 and 9 by replacing the term "growth phase" with a limitation defined by those individuals who actually experience such rapid growth - infants, children and adolescents.

The Examiner further contends that the present claims can be applied to an individual at anytime, because at least some of the claims are directed to compositions administered "prior to or in conjunction with an appetite-impacting stimulus." The Examiner contends that the human body constantly requires regular feeding for proper nutrition, so that when the claimed method is limited to administration prior to or at the time of an appetite-impacting stimulus, such administration could really be anytime at all.

Applicants would like to point out, however, that an appetite-impacting stimulus is defined in Applicants' Specification as a stressor or stimuli that may increase food intake, such as irregular meal times, sleep deprivation, and parental expectations to excel in school and/or sports (see Applicants' Specification, page 18, lines 24-32). If such a stimulus were with an individual continuously, as the Examiner suggests, then such an individual would always be hungry and, thus, have a continuous appetite for food. This is clearly not the case, at least for the vast majority of individuals.

Applicants respectfully submit that neither reference anticipates, inherently or otherwise, the claimed method.

It is well established that anticipation by inherency must be considered differently with respect to methods, as in the present case, as compared to compounds and devices. The consistent principle is that a benefit already provided to the public cannot be removed by discovery of an additional feature. Further advantages of a known compound or device do not increase what is already in the public domain. In contrast, appreciation of a previously unknown result achieved by an old method puts the public in possession of a new use. A method that has been practiced in the prior art, but without appreciation of a specific result, is not sufficient to anticipate a method for achieving that same unappreciated result. A method for achieving a specific result can be anticipated, however, by prior use of the same process steps for a purpose generic to the specific result.

For example, in the often-cited case of In re Caldwell, 138 USPQ 243, CCPA 1963, the court held that a prior art disclosure of feeding aspirin to rats did not render obvious a claimed method of stimulating growth of ruminants, poultry and swine by feeding aspirin, because the prior art did not suggest that feeding aspirin would stimulate growth.

In a more recent example, Perricone, M.D. v. Medicis Pharmaceutical Corp., Fed. Cir. December 20, 2005, the court held that a general disclosure of a similar lotion for topical application was insufficient to suggest the specific application to treating skin sunburn.

In the present application, and consistent with current case law, the claimed use of triacylglycerol esters of long chain n-3 polyunsaturated fatty acid compositions to reduce appetite to treat obesity or overweight in mammals that are obese or overweight is novel over the method of Cotter et al. (use for treating or preventing atherosclerotic, vascular, cardiovascular, or thrombotic diseases) as well as the method of Mazer et al (use for general infant and adult nutrition).

In view of the foregoing remarks, Applicants respectfully request withdrawal of the rejections under 35 USC 102 as it would apply to the amended claims.

Rejection under 35 USC 103

Claims 1-29 have been rejected under 35 USC 103(a) as being unpatentable over US Patent 4,920,098 (Cotter et al.) in view of U.S. Patent 6,200,624 (Mazer et al.) and WO 02/00042 (Jandacek et al.).

The Examiner contends that it would have been obvious to conduct routine dose optimization of the long chain polyunsaturated fatty acid formulations of the prior art, to thereby realize the present invention. Applicants respectfully traverse this rejection as it would apply to the amended claims.

Cotter et al. and Mazer et al. are summarized above.

Jandacek et al. discloses compositions comprising satiety agents selected from the group consisting of long chain fatty acids and their non-glyceryl esters, hydrolyzable in the presence of gastro-intestinal enzymes, wherein the satiety agent releases in the stomach (see page 3, lines 27-33). Jandacek et al. exclude the use of triacylglycerols as satiety agents, noting that triacylglycerols are hydrolyzed in the small intestine rather than the stomach (see page 5, lines 4-6) and will thus have little effect on food intake (see page 5, lines 12-15).

Applicants submit that the claimed methods are patentably distinct over the combination of Cotter et al., Mazer et al., and Jandacek et al., in that the prior art fails to disclose the specific use, as reflected in the amended claims, of triacylglyerol esters of long chain n-3 polyunsaturated fatty acids for reducing appetite to treat obesity and overweight in obese or overweight individuals. Cotter et al. discloses the use of similar compositions in individuals having or at risk of developing atherosclerotic, vascular, cardiovascular, or thrombotic diseases. (see Cotter et al., col. 1, lines 12-18). Mazer et al. discloses the use of similar compositions to provide infant and adult nutritional (column 1, lines 9 and 10). Jandacek et al. fails to disclose triacylglycerol esters of long-chain n-3

polyunsaturated fatty acid as satiety agents, and then repeatedly specifies the use of non-glycerol esters as satiety agents (see Jandacek et al, page 4, line 10; page 5, lines 4, 11-12, 24, and 26; page 7, line 3). In short, none of the applied references suggest the use of long chain n-3 polyunsaturated triacylglyerols as satiety agents to treat obesity or overweight in mammals that are obese or overweight.

To the contrary, not only does the combination of Cotter et al., Mazer et al, and Jandacek et al. fail to disclose the claimed use (reducing appetite to treat obesity and overweight in mammals that are obese or overweight), the Jandacek et al. reference actually teaches away from such use by suggesting that non-glycerol esters of long chain polyunsaturated fatty acids are effective as satiety agents, whereas their triacylglycerol ester counterparts are not (see Appeal Brief submitted on January 27, 2006). All of the present claims, by contrast, are limited to the use of triacylglycerol esters of long chain n-3 polyunsaturated fatty.

As noted earlier, Cotter et al. also teaches away from the present claims by advocating increased energy consumption for underweight individuals afflicted with various vascular diseases (col. 1, lines 67 and 68; col. 2, lines 1-3). Cotter et al. goes on to provide examples of such individuals (Examples 1-4; cols. 8-10), all of whom were given high calorie formulations (2.0 kcal/ml) comprising long chain polyunsaturated fatty acids (marine oil, GLA) (see col. 7, Tables II and III).

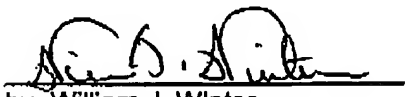
In view of the applied prior art, especially in view of Jandacek et al. and Cotter et al. as noted above, the skilled artisan would not then select the n-3 long chain polyunsaturated component from one of the prior art formulations to reduce appetite and treat obesity and overweight in accordance with the present claims.

In view of the foregoing remarks and those previously of record as they would apply to reapplication of the Jandacek et al. reference herein, Applicants respectfully request withdrawal of this rejection as it would apply to the amended claims.

Conclusion

Applicants respectfully request reconsideration of this application and allowance of claims 1-11.

Respectfully submitted,



by William J. Winter
Attorney for Applicants
Registration No. 36,060

Abbott Laboratories
Department 108140/S1
625 Cleveland Avenue
Columbus, OHIO 43215-1724
Phone (614) 624-5686; Fax (614) 624-3074